K072864

PREMARKET NOTIFICATION [510(K)] SUMMARY

MAR 13 2008

Date Prepared:	February 26, 2008
Submitter:	St. Jude Medical, CRMD
Address:	15900 Valley View Court Sylmar, CA 91324
Phone:	818 493-2960
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Contact Person:	Colleen Canan
Trade Name/Proprietary Name:	CPS Duo™ Left Heart Lead Delivery System
Common Name:	CPS Duo Guidewire, CPS Duo Stylet Model Numbers: DS2M001, DS2M002, DS2M005, DS2M006, DS2M007
Classification:	Class II, 21 CFR 870.1380 Class II, 21 CFR 870.1330
Legally marketed device to which your firm is claiming equivalence:	St. Jude Medical Model 4078S approved under (P030054) and Model 4078G approved under (K011084).

Device Description:

CPS Duo™ Left Heart Lead Delivery System is a combination of a CPS Duo™ Stylet and a CPS Duo™ Guidewire designed to facilitate the delivery of a SJM lead to the target vessel/site. The CPS Duo™ stylet has a lumen to allow a CPS Duo™ guidewire to pass through it. The CPS Duo™ Guidewire is specially designed to function in concert with the CPS Duo™ Stylet.

The CPS Duo™ Left Ventricular Lead Delivery System indication for use is as follows:

The St. Jude Medical CPS Duo™ Left Heart Lead Delivery system is designed to facilitate placement of SJM left heart leads to target vessel/site.

Technological Characteristics of the Device Compared to the Predicate Device:

The CPS Duo™ Left Heart Lead Delivery System, including the CPS Duo™ Stylet and the CPS Duo™ Guidewire use similar technology; have similar intended uses, functions, materials and method of operation of the following predicate devices.

- St. Jude Medical Model 4078S approved under (P030054) on June 30, 2004 and Model 4078G cleared under (K011084) on May 10, 2001.

Summary of Studies:

Device comparison testing was performed to support equivalency of the CPS Duo™ Left Heart Lead Delivery System with the predicate devices, SJM Models 4078S and 4078G. In addition verification testing was completed, including mechanical, functional and biocompatibility testing with the CPS Duo™ Left Heart Lead Delivery System meeting all specified design and performance specifications. Verification test report is in QTR 2179.

Biocompatibility:

St. Jude Medical has performed biocompatibility testing on the patient tissue contacting materials used in the CPS Duo™ Left Heart Lead Delivery System and have been found to be biocompatible. Biocompatibility testing (QTR 2143) is provided in appendix 4.

Sterilization Validation:

The CPS Duo™ Left Heart Lead Delivery System is sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion:

St. Jude Medical considers the CPS Duo™ Left Heart Lead Delivery System to be substantially equivalent to the legally marketed predicate and referenced devices. The results of the tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2008

St. Jude Medical
Cardiac Rhythm Management Division
Colleen Canan
15900 Valley View Court
Sylmac, CA 91342

Re: K072864
Trade/Device Name: CPS Duo™ Left Heart Lead Delivery System
Regulation Number: 21 CFR 870.1380
Regulation Name: Catheter stylet
Regulatory Class: Class II (two)
Product Code: DRB, DQX
Dated: February 26, 2008
Received: March 3, 2008

Dear Ms. Canan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K072864

Device Name: CPS Duo™ Left Heart Lead Delivery System

Indications for Use:

The CPS Duo™ guidewire and stylet are indicated for:

- Facilitation of placement of St. Jude Medical left heart leads to target vessel/site.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Summerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072864